REMARKS

Applicants thank the Examiner for the detailed Office Action dated 15 June 2006. Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and following remarks. Claims 1-41 were pending in the application. Claims 22-41 are requested to be canceled without prejudice or disclaimer. Claim 1 is currently being amended. Claims 42-53 are being added. After amending the claims as set forth above, claims 1-21 and 42-53 are now pending in this application.

For simplicity and clarity purposes in responding to the Office Action, Applicants' remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 1 and 14) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicants expressly reserve the right to argue the patentability of the dependent claims separately in any future proceedings.

Objection to the Abstract

On page 2 of the Office Action, the Patent Office objected to the abstract of the disclosure for using the word "invention." The Abstract has been amended to remove "invention." Accordingly, Applicants respectfully request that the objection be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Independent Claim 1

On page 3 of the Office Action, independent claim 1was rejected under 35 U.S.C. § 102(e) as being unpatentable over U.S. Patent No. 6,802,822 to Dodge. Applicants respectfully

traverse the rejection. Dodge does not identically disclose the subject matter recited in independent claim 1.

Applicants respectfully submit that Dodge does not identically disclose the combination of elements recited in independent claim 1. For example, independent claim 1 recites a "tissue puncture closure assembly" including, among other elements, a "vascular insertion sheath having a distal and a proximal end" wherein "the distal end of the insertion sheath comprises a tip portion that is stiffer than an insertion sheath portion adjacent to the tip portion," which is not identically disclosed in Dodge. Specifically, Dodge does not disclose a "vascular insertion sheath." Rather, the device in Dodge is a sealant dispenser used to dispense adhesive sealants and other liquid preparations in order to bond tissue after surgery. Dodge, title, abstract, col. 1, lines 7-9. Applicants note in this regard that the PTO acknowledges that the "identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); see MPEP § 2131.

Applicants respectfully submit that independent claim 1 is not anticipated by Dodge under 35 U.S.C. § 102(e) and is patentable.

Claim Rejections – 35 U.S.C. § 103(a)

Independent Claim 1

On page 4 of the Office Action, independent claim 1 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,861,004 to Kensey et al. in view of U.S. Patent No. 6,096,012 to Bogert et al.. Applicants respectfully traverse the rejection.

The Office Action does not make it clear how Kensey et al. and Bogert et al. would be combined to result in the subject matter recited in independent claim 1. Applicants understanding of the Office Action is that the Patent Office is asserting that it would be "obvious . . . to modify the [introducer sheath 28] of Kensey et al. with a stiffer tip portion as taught by Bogert et al. in order to enable insertion of the sheath into the body of the patient." If this is not the Patent Office's understanding, Applicants respectfully request additional clarification of the Patent Office's position.

Applicants respectfully submit that there is no motivation, teaching, or suggestion to combine the references in the manner asserted in the Office Action. The motivation provided in the Office Action is insufficient because it assumes that it would be desirable to modify an introducer sheath (*i.e.*, the introducer sheath 28 shown in Kensey et al.) to have the tip of a catheter/cannula combination (*i.e.*, the one-piece plastic catheter and cannula structure of Bogert et al.; see Bogert et al., col. 3, lines 12-18) so that the introducer sheath could be inserted into the body of the patient. Neither reference explains why it would be desirable to have an introducer sheath that can be inserted into the body of the patient like a cannula. In fact, Kensey et al. references a cannula, a catheter, and an introducer sheath at col. 4, line 52 to col. 5, line 4, however, Kensey et al. does not provide any motivation, teaching, or suggestion regarding why one would be motivated to combine them all into one unit as alleged in the Office Action. Likewise, although Bogert et al. describes combining a cannula and a catheter, there is no motivation, teaching, or suggestion why one would go the next step and combine the catheter/cannula combination with an introducer sheath as alleged in the Office Action. Since neither of the references provide a motivation, teaching, or suggestion to combine the cited

references, the Patent Office must provide some other evidence showing the necessary motivation, teaching, or suggestion. However, the Patent Office has failed to provide any additional evidence why one would make such a combination and has thus failed to make a prima facie case of obviousness.

Furthermore, Applicants note that the Patent Office has failed to consider other aspects of Kensey et al. which teach away from modifying the introducer sheath in the manner alleged in the Office Action. For example, the Patent Office has failed to explain why one would combine the "sharp needle point" of the catheter/cannula structure from Bogert et al. (see Bogert et al., col. 3, lines 12-18) with the introducer sheath 28 of Kensey et al. when it would appear that the "sharp needle point" presents a serious risk of cutting the filament 34 during deployment of the anchor 32 (see Kensey et al., Figures 16-24 and associated text discussion of anchor deployment).

The Patent Office has also failed to explain why one would combine the "sharp needle point" of the catheter/cannula structure from Bogert et al. with the introducer sheath 28 of Kensey et al. in view of the problems this would cause during the anchor deployment process. For example, if the distal tip of the introducer sheath 28 in Kensey et al. had the sloping tip shown in Bogert et al., it would be difficult, if not impossible, to determine whether the anchor 32 had been deployed correctly using the positioning clip 150 because this process relies on the anchor catching on the distal side of the introducer sheath and the user noting the position of the luer fitting 112 relative to the positioning clip 150. (See Kensey et al., col. 11, line 44 to col. 12, line 27.) Since the tip is sloped, the anchor may engage the tip anywhere along the slope which would result in the luer fitting 112 being positioned in any of a number of locations relative to

the positioning clip 150. Since the user would no longer be able to determine whether the anchor deployed properly based on the position of the luer fitting 112 relative to the positioning clip 150, the whole purpose of the positioning clip would be frustrated. As another example, withdrawing the instrument 20 and setting the anchor 32 in the manner described in Kensey et al. would appear to be much more difficult if the distal tip of the introducer sheath 28 was sloped. The first step in the procedure is to make sure the anchor is "caught on the distal end of the introducer at the location of the hemispherical projection." (Kensey et al., col. 12, lines 15-18.) After that, the introducer and the instrument are withdrawn as a unit from the puncture, whilst swinging the unit toward the vertical as shown in Figure 19. (Kensey et al., col. 12, lines 38-41.) However, if the anchor is caught on the distal tip of the introducer and the distal tip of the introducer 28 is sloped, then swinging the unit vertically would, in many cases, cause the anchor to be positioned at a sloping angle relative to the puncture so that it would be more prone to slide through the puncture.

For the above reasons, Applicants respectfully submit that the subject matter recited in independent claim 1 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request withdrawal of the rejection of the claims under 35 U.S.C. § 103(a).

Independent Claim 14

On page 5 of the Office Action, independent claim 14 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kensey et al. in view of U.S. Patent No. 6,270,470 to Buck et al. Applicants respectfully traverse the rejection.

The Office Action does not make it clear how Kensey et al. and Buck et al. would be combined to result in the subject matter recited in independent claim 14. Applicants understanding of the Office Action is that the Patent Office is asserting that it would be "obvious . . . to modify the [introducer sheath 28] of Kensey et al. with a areas of increased stiffness as taught by Buck et al. in order to guide the sealing plug out of the sheath and into the body." If this is not the Patent Office's understanding, Applicants respectfully request additional clarification of the Patent Office's position.

Applicants respectfully submit that there is no motivation, teaching, or suggestion to combine the references in the manner asserted in the Office Action. The motivation provided in the Office Action is insufficient because it assumes that it would be desirable to guide the sealing plug in Kensey et al. in a manner similar to how the tampon is guided out of the tampon applicator in Buck et al.. Neither reference explains why it would be desirable to modify how the sealing plug guided like the tampon in Buck et al. The problems that Buck et al. sought to overcome – tampon applicator petals catching hair or tissue when the tampon was deployed and the petals returned to their original shape and tampons not expanding against the sides and/or walls of the greater transverse dimension of the vaginal cavity (Buck et al., col. 1, lines 30-35; col. 2, lines 64-64-67; col. 3, lines 35-38) – seem to be specific to tampons and not to closing angiotomies such as those described in Kensey et al. Specifically, catching hair or tissue with petals does not seem to be a problem in Kensey et al. since neither the carrier tube 102 (see Kensey et al., col. 12, lines 45-49) nor the introducer sheath 28 have any petals. Also, the tissue puncture in Kensey et al. appears to be significantly more cylindrical than the shape of the vagina making it unnecessary for the sealing plug in Kensey et al. to deploy in the manner

disclosed for the tampon in Buck et al. Since neither of the references provide a motivation, teaching, or suggestion to combine the cited references, the Patent Office must provide some other evidence showing the necessary motivation, teaching, or suggestion. However, the Patent Office has failed to provide any additional evidence why one would want a sealing plug in an angiotomy context to deploy like a tampon.

Applicants also submit that the Patent Office has failed to consider other aspects of Kensey et al. which teach away from modifying the introducer sheath in the manner alleged in the Office Action. For example, the Patent Office has failed to explain why one would be motivated to guide the sealing plug in Kensey et al. using a tip having two openings as shown in Buck et al. when the sealing plug in Kensey et al. is "in the form of an elongated rod-like plug." (Kensey et al., col. 5, lines 36-38.) It appears that the single plug of Kensey et al. would exit out of one or the other of the two holes and thereby be directed away from being positioned directly over the puncture – something that seems very undesirable since Kensey et al. is seeking to close the puncture.

Applicants respectfully submit that the subject matter recited in independent claim 14 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request withdrawal of the rejection of the claims under 35 U.S.C. § 103(a).

New Claims

Applicants have added new claims 42-53, of which only claim 42 is in independent form. Independent claim 42 recites a "vascular insertion sheath" comprising a "flexible tubular member having a distal end and a proximal end" and a "hemostatic valve coupled to the

proximal end of the flexible tubular member" wherein "the distal end of the flexible tubular member includes a tip portion that is stiffer than a portion of the flexible tubular member positioned adjacent to the distal end," which is not taught or suggested by the cited references.

Applicants respectfully put the Patent Office and all others on notice that all arguments, representations, and/or amendments contained herein are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application including any patents or patent applications which claim priority to this patent application and/or any patents or patent applications to which priority is claimed by this patent application.

Applicants respectfully submit that the present Application is in condition for allowance. Applicants request reconsideration and allowance of the pending claims. The Examiner is invited to contact the undersigned by telephone if the Examiner needs anything or if a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date: 12 OCTOBER 2006

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